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Buprenorphine versus methadone in the treatment of pregnant opioid-dependent patients: effects on the neonatal abstinence syndrome.

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MEDLINE ABSTRACT

This study was designed to compare the neonatal abstinence syndrome (NAS) in neonates of methadone and **buprenorphine** maintained pregnant opioid-dependent women and to provide preliminary safety and efficacy data for a larger multi-center trial. This randomized, double-blind, double-dummy, flexible dosing, parallel-group controlled trial was conducted in a comprehensive drug-treatment facility that included residential and ambulatory care. Participants were opioid-dependent pregnant women and their neonates. Treatment involved daily administration of either sublingual **buprenorphine** or oral methadone using flexible dosing of 4-24 mg or 20-100 mg, respectively. Primary a priori outcome measures were: (1) number of neonates treated for NAS; (2) amount of opioid agonist medication used to treat NAS; (3) length of neonatal hospitalization; and (4) peak NAS score. Two of 10 (20%) **buprenorphine**-exposed and 5 of 11 (45.5%) methadone-exposed neonates were treated for NAS (p=.23). Total amount of opioid-agonist medication administered to treat NAS in methadone-exposed neonates was three times greater than for **buprenorphine**-exposed neonates (93.1 versus 23.6; p=.13). Length of hospitalization was shorter for **buprenorphine**-exposed than for methadone-exposed neonates (p=.021). Peak NAS total scores did not significantly differ between groups (p=.25). Results suggest that **buprenorphine** is not inferior to methadone on outcome measures assessing NAS and maternal and neonatal safety when administered starting in the second trimester of pregnancy.